



**SHEPHERD
CENTER**

A Specialty Hospital

2020 Peachtree Rd. NW
Atlanta, Georgia 30309
Tel (404) 352-2020

7007 '00 JUL 19 A9:24

July 11, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Number 00N-1357

To Whom It May Concern:

I am very pleased that the F.D.A. is addressing this issue.

I am 100% in support of pharmacies NOT being allowed to compound sterile products from nonsterile products. The example you cited in the article was using nonsterile morphine powder or tablets to make a sterile product which is in turn injected into the blood stream or intrathecal cavity. I consider this practice VERY dangerous. I know for a fact that this is a common practice.

I also am against pharmacies being able to compound transdermal patches. As you mentioned many of the pharmacies doing the compounding have not performed the proper tests to ensure stability and efficacy. Again, I know for a fact that many pharmacies are compounding transdermal patches. The patch that I have the most knowledge with is Procarin®. If the F.D.A. does prohibit pharmacies from compounding transdermal patches Procarin® would be affected. The pharmacy organization P.C.C.A. sells the Procarin® recipe to pharmacies. This business would need to be notified that this practice has been prohibited. Their phone number is 800-331-2498. I feel like P.C.C.A. has been very unethical in their dealings with the product Procarin®. That is an issue all to itself. I would like to discuss it further if you so desire.

I am a registered pharmacist with my doctorate degree. I do a tremendous amount of ethical compounding and feel like compounding is important. However, certain products need to be manufactured not compounded in order to provide for the safety of consumers.

Sincerely:

Ellen Whipple, Pharm D

Ellen Whipple, Pharm. D.
Apothecary Manager of the Shepherd Center
800-221-9373

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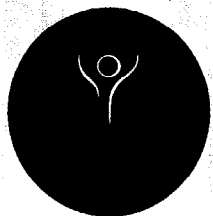


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00N-1357

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CENTER**
APOTHECARY

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Atlanta, Georgia 30309

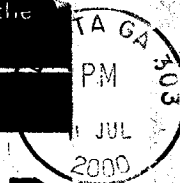
Docket
Number:
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